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Interventions to reduce tobacco use in people experiencing homelessness (Protocol)

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[Intervention Protocol]

Interventions to reduce tobacco use in people experiencing homelessness

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess whether interventions designed to improve access to smoking cessation interventions for adults experiencing homelessness and interventions designed to help adults experiencing homelessness to quit smoking lead to increased engagement and tobacco abstinence. To also assess whether smoking cessation interventions for adults experiencing homelessness affect substance use and mental health.

BACKGROUND

Description of the condition

Tobacco use is disproportionately concentrated among low-income populations, with rates exceeding that of the general population at least two-fold (Jamal 2015). Among low-income populations, such as people experiencing homelessness, estimated smoking prevalence ranges between 60% and 80% (Baggett 2013). Individuals with severe mental health disorders and/or substance use disorders who belong to racial/ethnic minority groups, who are older, or who self-identify as a gender and sexual minority are disproportionately represented in populations experiencing homelessness (Culhane 2013; Fazel 2014). The prevalence of mental health and substance use disorders is high among people experiencing homelessness. A systematic review concluded that the most common mental health disorders among this population were drug (range 5% to 54%) and alcohol dependence (range 8% to 58%), and that the prevalence of psychosis (range 3% to 42%) was as high as that of depression (range 0% to 59%) (Fazel 2008). These populations carry a high burden of tobacco use and tobacco-related morbidity and mortality (Schroeder 2009). Persons experiencing homelessness are three to five times more likely to die prematurely than those who are not homeless (Baggett 2015; Hwang 2009), and tobacco-related chronic diseases are the leading causes of morbidity and mortality among those aged 45 and older (Baggett 2013b). Among younger homeless-experienced adults (< 45 years), the incidence of tobacco-related chronic diseases is three times higher than the incidence in age-matched non-homeless adults (Baggett 2013b).

Persons experiencing homelessness have distinctive tobacco use behaviors associated with low income, substance use comorbidities,

and housing instability that affect their likelihood of successfully quitting. Epidemiological studies of tobacco use among this population have shown that most adults experiencing homelessness initiate smoking before the age of 16 (Arnsten 2004). Average daily cigarette consumption is between 10 and 13 cigarettes per day, and more than one-third smoke their first cigarette within 30 minutes of waking (Okuyemi 2006; Vijayaraghavan 2015; Vijayaraghavan 2017). People experiencing homelessness have high rates of concurrent use of alternative tobacco products such as little cigars, smokeless tobacco, and e-cigarettes (Baggett 2016; Neisler 2018). They also engage in high-risk smoking practices including exposure compensation when reducing cigarettes smoked per day and smoking cigarette butts (Garner 2013; Vijayaraghavan 2018). Smoking norms include sharing or "bumming" cigarettes, and these practices may reduce the effects of policy interventions such as increased taxes (Garner 2013; Vijayaraghavan 2018). Individuals experiencing homelessness face significant barriers to cessation, including disproportionately high rates of post-traumatic stress disorder (PTSD), which can lead to positive associations with smoking (Baggett 2016a). Smoking cessation is challenging for people who have to navigate the stressors of homelessness (Baggett 2018; Chen 2016), high levels of nicotine dependence, and limited access to smoking cessation treatment and smoke-free living environments (Vijayaraghavan 2016; Vijayaraghavan 2016b). Integrating tobacco dependence treatment into existing services for homeless-experienced adults remains challenging (Vijayaraghavan 2016b). Staff members may not support quit attempts (Apollonio 2005; Garner 2013), and homeless-experienced adults do not have consistent access to services or information technologies used to improve access to cessation interventions (McInnes 2013).

Despite these challenges, over 40% of adults experiencing homelessness report making a quit attempt in the past year (Baggett 2013c; Connor 2002). A majority relapse to smoking, with estimates of the quit ratio (i.e. the ratio of former-to-ever smokers) between 9% and 13% compared to 50% in the general population (Baggett 2013c; Vijayaraghavan 2016).

Homeless populations have been historically neglected in population-wide tobacco control efforts; however, there has been increasing interest in studying the correlates of tobacco use and cessation behaviors for these populations and in discovering how these individuals may differ from the general population (Goldade 2011; Okuyemi 2013). Typically high levels of nicotine dependence among adults experiencing homelessness are associated with low likelihood of quitting (Vijayaraghavan 2014). Proximity to a shelter during the week after a quit attempt has been associated with higher risk of relapse, thought to occur because of increased exposure to environmental cues to smoking (Businelle 2014; Reitzel 2011). In contrast, staying in a shelter, as opposed to on the street, has been associated with quitting smoking (Vijayaraghavan 2016), possibly due to exposure to shelter-based smoke-free policies. Studies have shown that engaging in smoking cessation does not adversely affect substance use behaviors (Apollonio 2016), and has increased the number of days abstinent from alcohol (Reitzel 2014). More recent research efforts such as have focused on designing interventions to reduce smoking initiation among youth experiencing homelessness (Shadel 2014), and to improve quit rates among adults experiencing homelessness (Baggett 2017; Carpenter 2015; Ojo-Fati 2015; Okuyemia 2006b; Okuyemi 2013; Rash 2018).

Description of the intervention

Interventions designed to support people to stop smoking can work to motivate people to attempt to stop smoking ("cessation induction"), or to support people who have already decided to stop to achieve abstinence ("aid to cessation"). In this review, we will include both types of interventions. Many people who are homeless face barriers to using regular services, such as healthcare services, through which cessation support is available. The availability of support to assist a quit attempt can itself create motivation to quit (Aveyard 2012). Thus one possible intervention to support people experiencing homelessness is to provide bespoke cessation services that can operate both to make quitting seem more desirable and to provide treatment for those who are attempting to stop smoking. The combination of behavioral counseling and pharmacotherapy (nicotine replacement therapy [NRT], bupropion, or varenicline) is the gold standard for individually tailored smoking cessation treatment in the general population (Stead 2016). However, a vast majority of quit attempts made by people experiencing homelessness are unassisted (Vijayaraghavan 2016). Preference for cessation aids may vary by cigarette consumption, with light smokers (0 to 10 cigarettes per day) preferring counseling over medication, in contrast to moderate/heavy smokers (> 10 cigarettes per day) (Nguyen 2015).

How the intervention might work

Cessation induction interventions directed at smokers who are not ready to quit rely on pharmacological, behavioral, or combination interventions to increase motivation and intention to quit, with an eventual goal of abstinence. Interventions may include nicotine therapy sampling to induce practice quit attempts, as described in Carpenter 2011, or motivational interviewing to induce cessation-related behaviors among smokers who are not motivated to quit, as examined in Catley 2016.

Tobacco dependence treatment can provide motivation and support for change through pharmacotherapy (Cahill 2013), counseling (Lancaster 2017), financial incentives (Notley 2019), or a combination of these (Stead 2016). Pharmacotherapy can reduce the urge to smoke and can decrease nicotine withdrawal symptoms via NRT, varenicline, or bupropion (Cahill 2013); counseling can provide support and motivation to make and continue with quit attempts (Lancaster 2017). For individuals with severe tobacco dependence, such as people experiencing homelessness,

multi-component interventions that include behavioral counseling, combination pharmacotherapy, and other adjunctive methods such as financial incentives - as discussed in Businelle 2014b, Baggett 2017, and Rash 2018 - or mobile support - as offered in Carpenter 2015 - may be beneficial. However, as many quit attempts are unassisted, more may need to be done to remove barriers and facilitate access to cessation support for smokers who are homeless.

Why it is important to do this review

People experiencing homelessness have unique tobacco use characteristics, including higher likelihood of irregular smoking patterns, reduced exposure to clean indoor air policies, and reliance on "used" cigarettes (Baggett 2016; Garner 2013; Vijayaraghavan 2018). They receive limited support for cessation from service providers (Apollonio 2005; Garner 2013). Many countries have identified homeless-experienced adults as a high-risk group in need of targeted interventions (Fazel 2014). Tobacco use is the single most preventable cause of mortality among adults experiencing homelessness (Baggett 2015). Past efforts to promote tobacco cessation among this population have yielded mixed results that make it difficult to assess which types of tobacco dependence treatments promote abstinence. Our findings will synthesize evidence to date and will identify interventions that increase quit attempts and abstinence, as well as improve access to treatment, for this vulnerable population. We will also explore whether cessation interventions affect mental health or substance use outcomes among this population.

OBJECTIVES

To assess whether interventions designed to improve access to smoking cessation interventions for adults experiencing homelessness and interventions designed to help adults experiencing homelessness to quit smoking lead to increased engagement and tobacco abstinence. To also assess whether smoking cessation interventions for adults experiencing homelessness affect substance use and mental health.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomized controlled trials (RCTs) and cluster RCTs, with no exclusions based on language of publication or publication status.

Types of participants

Participants will include homeless and unstably housed adults (> 18 years of age). This will be defined by criteria specified by individual studies; however we envisage that participants will meet one or more of the following criteria for homelessness (ANHD 2018; Council to Homeless Persons 2018; Fazel 2014).

1. Individuals and families who do not have a fixed, regular, and adequate night-time residence, including individuals who live in emergency shelters for homeless individuals and families, and those who live in places not meant for human habitation.
2. Individuals and families who will imminently lose their main night-time residence.
3. Unaccompanied young adults and families with children and young people who meet other definitions of homelessness.
4. Individuals and families who are fleeing or attempting to flee domestic violence, dating violence, sexual assault, stalking, or other dangerous or life-threatening conditions that relate to violence against an individual or family member.
5. Individuals and families who live in transitional shelters or housing programs.
6. Individuals and families who are temporarily living with family or friends.
7. Individuals and families who are living in overcrowded conditions.

Participants must also be tobacco users who may or may not be motivated to quit.

Types of interventions

We will include in our review any interventions that:

1. focus on increasing motivation to quit, building capacity (e.g. providing education or training to provide cessation support to staff working with people who are homeless), or improving access to tobacco cessation services in clinical and non-clinical settings for homeless adults;
2. aim to help people making a quit attempt to achieve abstinence, including but not limited to behavioral support, tobacco cessation pharmacotherapies, contingency management, and app-based interventions; or
3. focus on transitions to long-term nicotine use that do not involve combustible tobacco.

Control groups may receive no intervention or 'usual care', as defined by individual studies.

Types of outcome measures

Primary outcomes

1. Tobacco abstinence (given the paucity of data on long-term cessation outcomes among people experiencing homelessness, we will also assess short-term cessation outcomes), assessed at three time points
   i) Short-term abstinence: < three months after quit day
   ii) Medium-term abstinence: ≥ three months and < six months after quit day
   iii) Long-term abstinence: ≥ six months after quit day

We will conduct separate analyses for each time point. We will use the strictest definition of abstinence used by the study, with preference for continuous or prolonged (allowing a grace period for slips) abstinence over point prevalence abstinence. When possible, we will extract biochemically verified rates (e.g. breath carbon monoxide, urinary/saliva cotinine) over self-report. We will assess abstinence on an intention-to-treat basis, using the number of people randomized as the denominator.

Secondary outcomes

1. Number of participants receiving treatment
2. Number of people making at least one quit attempt as defined by included studies
3. Abstinence from alcohol and other drugs as defined by self-reported drug use or through biochemical validation (or both), at the longest follow-up period reported in the study
4. Point prevalence or continuous estimates (e.g. questionnaire scores) for mental illnesses (including major depressive disorder, generalized anxiety disorder, post-traumatic stress disorder, schizophrenia, and bipolar disorder) as defined by previously validated survey instruments or physician diagnosis

Search methods for identification of studies

Electronic searches

We will search the Cochrane Tobacco Addiction Group Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL), and MEDLINE. The MEDLINE search strategy is provided in Appendix 1. The Specialized Register includes reports of tobacco-related trials identified through research databases, including MEDLINE, Embase, and PsycINFO, as well as via trial registries and handsearching of journals and conference abstracts. For a detailed account of searches carried out to populate the Register, see the Cochrane Tobacco Addiction Group's website.

Searching other resources

We will search grey literature, including conference abstracts from the Society for Research on Nicotine and Tobacco. We will contact investigators in the field about potentially unpublished studies. We will additionally search for registered unpublished trials through the National Institutes of Health clinical trials registry (www.clinicaltrials.gov) and the World Health Organization International Clinical Trials Registry Platform Search Portal (http://apps.who.int/trialsearch/).

Data collection and analysis

Selection of studies

We will merge search results using reference management software and will remove duplicate records. Two independent review authors (MV and HS) will examine the titles and abstracts to identify relevant articles and will subsequently retrieve and examine the full-text articles to assess adherence with the eligibility criteria. A third review author (DA) will independently assess whether the full-text articles meet eligibility criteria. We will exclude all studies that do not meet inclusion criteria in terms of study design, population, or interventions. We will resolve disagreements by discussion, and when necessary, the third review author will arbitrate the case.

Data extraction and management

Two review authors (MV and HS) will independently extract data in duplicate. We will contact study authors to obtain missing outcome data. Once outcome data have been extracted, one of the review authors (MV) will enter them into Review Manager 5.3, and another (HS) will check them (Higgins 2011). All review authors (MV, HS, and DA) will extract information from each study for risk of bias assessments.

We will extract he following information from study reports using a template developed by DA and modified by MV.

1. Source, including study ID, report ID, reviewer ID, citation, contact details, and country.
2. Methods, including study design, study objectives, study site, study duration, blinding, and sequence generation.
3. Participant characteristics, including total number enrolled and number in each group, setting, eligibility criteria, age, sex, race/ethnicity, sociodemographics, tobacco use (type, dependence level, amount used), mental illness, substance use, other comorbidities, and current residence (unsheltered, sheltered, single room occupancy hotel or temporary residence, or supportive housing).
4. Interventions, including total number of intervention groups and comparisons of interest, specific intervention, intervention details, and integrity of the intervention.
5. Outcomes, including definition, unit of measurement, and time points collected and reported.
6. Results, including participants lost to follow-up, summary data for each group, and subgroup analyses.

7. Miscellaneous items, including study author conflicts of interest, funding sources, and correspondence with study authors.

Assessment of risk of bias in included studies

Two review authors will assess the risk of bias for each included study, as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*, Chapter 8 (Higgins 2011). Using a risk of bias table, we will categorize risk of bias as "low risk," "high risk," or "unclear risk" for each domain, with the last category indicating insufficient information to judge risk of bias. We will assess the following domains: selection bias (including sequence generation and allocation concealment), blinding (performance bias and detection bias), attrition bias (incomplete outcome data), and any other bias. According to guidance from the Cochrane Tobacco Addiction Group, we will assess performance bias only for studies of pharmacotherapies, as it is impossible to blind behavioral interventions.

Measures of treatment effect

When possible, we will report a risk ratio (RR) and 95% confidence intervals (CIs) for the primary outcome (i.e. abstinence) for each included study. The risk ratio is defined as (number of participants in the intervention group who achieve abstinence/ total number of people randomized to the intervention group)/ (number of participants in the control group who achieve abstinence/total number of people randomized to the control group). We will use an intention-to-treat analysis, in which participants are analyzed based on the intervention to which they were randomized, irrespective of the intervention they actually received. For dichotomous secondary outcomes, such as number of people making a quit attempt and abstinence from substance use, we will calculate an RR with 95% CI for each study. For any continuous measures of our mental illness secondary outcome, we will calculate the mean difference (MD) or the standardized mean difference (SMD), as appropriate for each study.

Unit of analysis issues

The unit of analysis will be the individual. For cluster-randomized trials, we will assess whether study authors have adjusted for this clustering, and whether this had an impact on the overall result. When clustering appears to have had little impact on the results, we will use unadjusted quit rate data; however when clustering does appear to have an impact on results, we will adjust for this using the intraclass correlation (ICC).

Dealing with missing data

When outcome data are missing, we will attempt to contact the study authors to request missing data. For all outcomes apart from mental health, we will assume that participants who are lost to follow-up are continuing smokers, are still using other substances, did not make a quit attempt, or did not receive treatment. We will report deaths separately and will not include participants who have died during the analysis. For the mental health outcome, we will conduct a complete case analysis.

Assessment of heterogeneity

We will classify heterogeneity as clinical, methodological, or statistical (Higgins 2011). We will not attempt a meta-analysis if we observe significant clinical or methodological heterogeneity between studies; we will instead report results in a narrative summary. If we feel it is appropriate to carry out meta-analyses, we will assess statistical heterogeneity using the I^2 statistic, which represents the percentage of the effect that is attributable to heterogeneity versus chance alone (Chapter 9; Higgins 2011). We will consider an I^2 value greater than 50% as evidence of substantial heterogeneity.

Assessment of reporting biases

We will assess several forms of reporting bias including outcome reporting bias (selective reporting of outcomes), location bias (publication of research in journals that may have different levels of access such as open access publication), and publication bias (publication or non-publication of studies depending on the direction of outcome effects), and we will discuss these in our review. We will assess whether abstinence from tobacco, our primary outcome, was reported in all included studies, and will report which studies included this outcome and which did not. If we include more than 10 studies in any analyses, we will generate a funnel plot to help us assess whether there could be publication bias.

Data synthesis

When meta-analysis is appropriate, we will use the Mantel-Haenszel random-effects method to calculate pooled, summary, weighted risk ratios (95% CIs), or inverse-variance random-effects methods to calculate pooled, summary, weighted MDs (95% CIs) or SMDs (95% CIs). We will pool separately studies testing interventions that aim to improve access to smoking cessation interventions and studies that are simply testing the effectiveness of smoking cessation interventions among people experiencing homelessness. Should meta-analyses not be possible, we will provide a narrative assessment of the evidence.

Subgroup analysis and investigation of heterogeneity

When possible, we will conduct subgroup analyses to examine whether outcomes differ based on:

1. intensity of treatment (e.g. number of counselling sessions);
2. participants' residential history (sheltered vs unsheltered);
3. participants' substance use history;

4. participants' diagnosis of mental health disorder; and
5. participants' use of non-cigarette tobacco and nicotine products.

Sensitivity analysis

We will conduct sensitivity analyses by excluding studies with high risk of bias (judged to be at high risk for one or more of the domains assessed).

Summary of findings

We will produce a "Summary of findings" table (Higgins 2011), presenting the primary outcome (tobacco use abstinence at all time points), absolute and relative magnitude of effects, numbers of participants, and numbers of studies contributing to these outcomes. Two independent review authors will also carry out GRADE assessments of the certainty of evidence. Using GRADE criteria (study limitations, consistency of effect, imprecision, indirectness, and publication bias), we will grade the quality of evidence as very low, low, moderate, or high, and will provide footnotes to explain reasons for downgrading of evidence.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. (un-housed* OR homeless* OR "unstably housed" OR runaway OR "homeless persons"[mesh] OR housing instability)
2. ((smoking cessation.mp. OR exp Smoking Cessation/) OR "Tobacco-Use-Cessation"/ OR "Tobacco-Use-Disorder"/ OR Tobacco-Smokeless/ OR exp Tobacco-/ OR ((quit$ or stop$ or ceas$ or giv$) adj5 smoking).ti,ab.)) OR exp Smoking/)
3. ((randomised controlled trial[pt]) OR (controlled clinical trial[pt]) OR (clinical trial[pt])) OR ((pragmatic clinical trial)) NOT (animals[mh]))
4. 1 AND 2 AND 3

CONTRIBUTIONS OF AUTHORS

The protocol was conceived and prepared by Maya Vijayaraghavan, Holly Elser, and Dorie Apollonio.

DECLARATIONS OF INTEREST

Maya Vijayaraghavan has no conflicts of interest to report. MV has one pending grant application on the topic of smoke-free policies in permanent supportive housing for formerly homeless populations.

Holly Elser has no conflicts of interest to report.

Dorie Apollinio has no conflicts of interest to report.

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